

JUN 22 2006

**510(k) Summary for the
Dimension® Extended Range
Cyclosporine Calibrator Catalog # DC108A**

A. 510(k) Number: *k06/503*

B. Analyte: Cyclosporine Calibrator

C. Type of Test: Calibrator Material

D. Applicant:

Manufacturer: Dade Behring Inc., P.O. Box 6101, Newark, DE 19714-6101

Contact: Andrea M. Tasker, Regulatory Affairs and Compliance Manager
(302) 631-9454

Date of Preparation: May 31, 2006

E. Proprietary and Established Names:

Dimension® Extended Range Cyclosporine Calibrator (DC108A)

F. Regulatory Information:

1. Regulation section: 862.3200 - CLINICAL TOXICOLOGY CALIBRATOR
2. Classification: Class II
3. Product Code: DLJ - CALIBRATORS, DRUG SPECIFIC
4. Panel: CLINICAL TOXICOLOGY

G. Intended Use:

1. Intended use(s):

The Dimension® CSAE Cyclosporine Extended Range Calibrator is an in vitro diagnostic product intended to be used to calibrate the CSAE Cyclosporine Extended range method for the Dimension® clinical chemistry system and the Syva® Emit® 2000 Cyclosporine assay.

2. Indication(s) for use:

The Dimension® CSAE Cyclosporine Extended Range Calibrator is an in vitro diagnostic product intended to be used to calibrate the CSAE Cyclosporine Extended range method for the Dimension® clinical chemistry system and the Syva® Emit® 2000 Cyclosporine assay.

3. Special condition for use statement(s): none

4. Special instrument Requirements: none

H. Device Description:

The Dimension® CSAE Cyclosporine Extended Range Calibrator contains cyclosporine in a preserved whole blood hemolysate. The kit consists of 2 sets of the following: one vial of sample diluent (0.0 ng/ml of cyclosporine) and one vial of levels 1 through 5. Target concentrations for the five calibrator levels are approximately 200, 400, 800, 1400 and 2000 ng/ml of cyclosporine.

Level 0 is included for dilution of over-range samples (>2000 ng/mL) in order to obtain results within the assay range; it is not used in calibration. Levels 1 thru 5 are used for calibration of the CSAE method.

I. Substantial Equivalence Information:

1. Predicate device name(s): Dimension® CSAE Cyclosporine Extended Range Calibrator (DC108)

2. Predicate K number(s):

K052015, Dimension® Cyclosporine Extended Range Calibrator (CSAE CAL – DC108)

cleared on September 12, 2005 for the Dimension® system intended use

K053108, Dimension® Cyclosporine Extended Range Calibrator (CSAE CAL – DC108)

cleared on January 12, 2006 for new Syva® Emit® 2000 intended use

3. Comparison with predicate:

Similarities		
Item	New Device	Predicate
	Dimension® CSAE Cyclosporine Calibrator DC108A	Dimension® CSAE Cyclosporine Calibrator DC108
Intended Use	The Dimension® CSAE Cyclosporine Extended Range Calibrator is an in vitro diagnostic product intended to be used to calibrate the CSAE Cyclosporine Extended range method for the Dimension® clinical chemistry system and	The Dimension® CSAE Cyclosporine Extended Range Calibrator is an in vitro diagnostic product intended to be used to calibrate the CSAE Cyclosporine Extended range method for the Dimension® clinical chemistry system and

	the Syva® Emit® 2000 Cyclosporine assay.	the Syva® Emit® 2000 Cyclosporine assay.
Matrix	Preserved whole blood hemolysate	Preserved whole blood hemolysate
Number of levels used for calibration	5 Levels	5 Levels
Target Concentrations	200, 400, 800, 1400 and 2000 ng/ml of cyclosporine	200, 400, 800, 1400 and 2000 ng/ml of cyclosporine
Storage	This is a frozen product	This is a frozen product
Differences		
Item	New Device	Predicate
	Dimension® CSAE Cyclosporine Calibrator DC108A	Dimension® CSAE Cyclosporine Calibrator DC108
Packaging	The kit consists of 6 <i>glass</i> Vials (Level 0 – Level 5), 2.0 mL each.	The kit consists of 6 <i>plastic</i> Vials (Level 0 – Level 5), 2.0 mL each.
Storage Temperature	Unopened vials should be stored between -15 and -25°C.	Unopened vials should be stored between -17 and -27°C.
Traceability (Reference lot Formulation)	Reference lot stock solution formulated Final Reference lot sent to external reference lab for LC/MS/MS value assignment	Reference lot stock solution formulated and tested by LC/MS Final Reference lot sent to external reference lab for LC/MS/MS value assignment

Value Assignment (New Calibrator Lot)	Stock solution for new Calibrator Lot formulated New Calibrator Lot recovery verses the Reference Lot and verses Control Calibrator lot (Control Calibrator Lot = Any Approved Calibrator Lot)	Stock solution for new Calibrator Lot formulated and tested by LC/MS New Calibrator Lot recovery verses the Reference Lot and verses Control Calibrator lot (Control Calibrator Lot = Any Approved Calibrator Lot)
Production Site	Calibrator manufactured by Dade Behring Inc. in Glasgow Delaware	Calibrator prepared by an OEM Manufacturer for Dade Behring Inc.

J. Standard/Guidance Document Referenced:

1. Guidance;
Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays;
Guidance for Industry and FDA, Document issued on: September 16, 2002.
2. Standards;
GP22-A Continuous Quality Improvement Essential Management Approaches
CEN 13640 Stability testing of In-Vitro Diagnostic Devices
ISO 14971:2000 Medical devices -Application of risk management to medical devices
ISO 15223 Medical devices – Symbols to be used with medical device labeling and information to be supplied

K. Test Principle:

The Dimension® CSAE Cyclosporine Extended Range Calibrator contains cyclosporine in a preserved whole blood hemolysate. It is intended to be used to calibrate the high range cyclosporine assay on the Dimension® clinical chemistry systems and the Syva® Emit® 2000 Cyclosporine assay.

L. Performance Characteristics:**1. Stability**

Target shelf life for the Dimension® CSAE Calibrator (DC108A) is 12 months. Studies require 13 months of real time testing on three lots of product. Calibrator shelf life is determined by comparing results of the product stored at -15 to -25°C (recommended storage temperature) with product stored at -70°C (reference storage temperature) to ensure that analytical system drift is dissociated with calibrator drift. Product is tested at days 0, 7, 14, 30, 90, 120, 150, 180, 210, 240, 270, 300, 330, 360, 390.

2. Traceability:

Novartis Pharmaceutical USP Grade CSA powder is used to formulate a reference stock solution. A reference lot is formulated by diluting the stock into whole blood hemolysate with preservatives at six different levels and stored -70° C. The reference lot is assigned by LC/MS/MS.

3. Value Assignment

A cyclosporine stock solution is prepared using standard gravimetric procedure. Aliquots of the stock solution are added to measured amounts of calibrator matrix to yield the desired concentration for each calibrator level. Cyclosporine calibrators are prepared in preserved whole blood hemolysate. The recovery of the six levels are verified verses a control calibrator lot (control calibrator = any approved calibrator lot) and verses the frozen reference lot.

M. Comments on Substantial Equivalence/Conclusion

The performance testing according to the verification and validation test protocols demonstrate that the Dimension® CSAE Calibrator (DC108A) is substantially equivalent to the designated predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 22 2006

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Andrea M. Tasker
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
Glasgow Business Community
PO Box 6101 MS 514
Newark, DE 19714-6101

Re: k061503
Trade/Device Name: Dimension® CSAE cyclosporine Extended Range Calibrator
Regulation Number: 21 CFR§862.3200
Regulation Name: Clinical toxicology calibrator
Regulatory Class: Class II
Product Code: DLJ
Dated: May 31, 2006
Received: June 1, 2006

Dear Ms. Tasker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

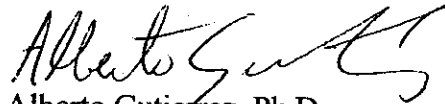
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Alberto Gutierrez', with a stylized flourish at the end.

Alberto Gutierrez, Ph.D.

Director

Division of Chemistry and Toxicology

Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K061503

Device Name:

Dimension® CSAE Cyclosporine Extended Range Calibrator

Indications for Use:

The Dimension® CSAE Cyclosporine Extended Range Calibrator is an in vitro diagnostic product intended to be used to calibrate the CSAE Cyclosporine Extended range method for the Dimension® clinical chemistry system and the Syva® Emit® 2000 Cyclosporine assay.

Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the-counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)


Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K061503